REMARKS

This is a response to the Office Action mailed March 11, 2004. Claims 1, 3, 5-7, 10-32, 37-39, 41-44 and 46-50, 53-59, 61 and 63-85 are pending in the application. Claims 1-3, 5-7, 10-32, 37-39, 41-44 and 46-85 have been rejected by the Examiner. As noted above, Applicants have amended Claims 1, 37-39, 42, 44, 46 and 53, and canceled Claims 2, 51, 52, 60 and 62 without prejudice. The amendments are fully supported by the written description. Also, no new matter has been introduced into the application.

Claim Rejections – 35 U.S.C. § 102

The Examiner has rejected Claims 1-3, 5-7, 10-29, 31, 32, 37-39, 41-44 and 46-85 under 35 U.S.C. §102(b) as being anticipated by Fishcell et al. (U.S. Patent No. 5,840,009). According to the Federal Circuit, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Fischell et al. clearly fails to disclose all of the limitations of the claimed invention. Applicants respectfully request the Examiner to consider the remarks for each individual claim mentioned below:

1. Claim 1

Fischell et al. does not disclose an elongated source including a therapeutic agent with an amount or a concentration that "**gradually decreases along a length of the elongated source from a point inward of a proximal end to or near the proximal end of the elongated source or from a point inward of a distal end to or near the distal end of the elongated source.**" Nowhere in Fischell et al. is it disclosed that the distribution of radioisotope decreases along the length of the stent from the center portion to the ends. Instead, as shown in Figure 2, non-uniform distribution **12** increases along the length from the center portion to the ends.

2. Claim 6

Fischell et al. does not disclose a stent having a radioactive region where "the radioactive region includes a segment gradually transitioning from the therapeutic level to a **non-therapeutic level** of radioactivity near the proximal end or the distal end of the radioactive region." Applicants respectfully request the Examiner to specifically identify the passage of Fischell et al. where it is disclosed that the radioactive level would be at a non-therapeutic level along the length of the stent body.

3. Claim 13

Fischell et al. does not disclose that "the radioactive region includes a segment gradually transitioning from the therapeutic level to a **non-therapeutic level** of radioactivity near the proximal end or the distal end of the radioactive region."

4. Claim 21

Fischell et al. fails to disclose a gradient that "**decreases the dose from a point inward of the proximal end to or near the proximal end, or decreases the dose from a point inward of the distal end to or near the distal end of the radioactive region.**" Nowhere in Fischell et al. is it disclosed that the distribution of radioisotope decreases along the length of the stent from the center portion to the ends. Instead, as shown in Figure 2, non-uniform distribution **12** increases along the length from the center portion to the ends.

5. Claim 31

Fischell does not disclose a stent including, "a **drug delivery** region along an elongated length of a stent, the drug delivery region having a **variable drug concentration** thereon." Fischell et al. merely discloses that "it may be advantageous to place an anti-thrombogenic coating on the surface of the stent either before (or preferably) after the radioisotope has been ion implanted into the stent." Col. 2, line 67 to col. 3, line 3. This very limited disclosure related to drug coatings should not be interpreted to mean that the Fischell et al. stent would have a drug

gradient on the body of the stent. For one, there is absolutely no disclosure in Fischell et al. describing how such a drug gradient would be formed.

Fischell et al. also fails to disclose that the stent would include "a drug concentration gradient near a proximal end or a distal end of the drug delivery region, the drug concentration gradient gradually **decreasing** from a therapeutic dose level to a non-therapeutic dose level, and **wherein the gradient decreases from a point inward of the proximal end to or near the proximal end, or decreases from a point inward of the distal end to or near the distal end of the drug delivery region**." Applicants respectfully ask the Examiner to point out where in Fischell et al. a drug gradient is described in which the concentration of drug on the stent decreases from the middle portion of the stent to the ends.

6. Claim 37

Fischell et al. does not disclose, "forming a **drug concentration** gradient within the drug region near the proximal end and/or the distal end of the drug region, the concentration gradients gradually transitioning the drug concentration from the therapeutic level of drug concentration to a **non-therapeutic level of drug concentration**." Fischell et al. merely discloses a stent with a non-uniform distribution of radioisotope that can also include an anti-thrombogenic coating. First, one of ordinary skill in the art clearly understands that **"radioactivity" is not equivalent to a "drug compound."** The distinction between these two types of therapeutic agents is clearly set-forth throughout the present application, for example in at least paragraphs 23 and 50-66. If the Examiner contends that radioactivity should be considered the same as a drug compound for the purposes of this area of art, Applicants request the Examiner to provide documentary proof of such equivalency.

Second, there is nothing in Fishcell et al. that even suggests the anti-thrombogenic coating should have a **non-therapeutic level** of drug concentration along a portion of the stent, let alone a portion near the ends of the stent.

7. Claim 41

Fishcell et al. does not disclose producing a drug gradient by "**dipping** the drug source in a drug or **spraying** a drug onto the drug source." Fishell et al. merely discloses "placing" an anti-thrombogenic coating on the stent.

8. Claim 42

Fishcell et al. does not disclose producing a drug gradient by "using **masking techniques**."

9. Claim 44

Fishcell et al. does not disclose producing a drug gradient by "**spraying** a drug composition onto the drug source and **varying the amount of the drug in the composition as the drug composition is sprayed onto the drug source**."

10. Claim 46

Fischell et al. fails to disclose a stent including a therapeutic agent where "the concentration or amount of therapeutic agent gradually changes by **incremental segments** along the length of the stent or at a **constant rate** along a length of the stent." As shown in Figure 2, Fischell et al. merely discloses that the distribution of the radioisotope changes at a variable rate. The distribution, therefore, does not change gradually "by incremental segments" or "at a constant rate." The Examiner is invited to compare Figure 2 of Fischell et al. with Figures 4-6 of the present invention to see the distinction.

11. Claim 53

Fischell et al. does not disclose a method that includes "depositing a therapeutic agent onto a body of a stent, wherein the amount or concentration of the therapeutic agent deposited onto the body gradually changes along a length of the stent, and wherein the therapeutic agent is **deposited so that the concentration or amount changes at a constant rate along the length of stent or in incremental segments along the length of the stent.**" As noted above, Fischell

et al. merely discloses that the distribution of the radioisotope changes at a variable rate. See Figure 2 in Fischell et al.

12. Claim 63

Fischell et al. does not disclose a stent having a drug where "**the middle segment of the stent has more of the drug than the first or second end of the stent.**" Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and teaches nothing regarding the amount of drug applied to different portions of the stent.

13. Claim 64

There is nothing in Fischell et al. to even suggest that the "anti-thrombogenic coating" would include a **polymer**.

14. Claim 65

Fischell et al. does not disclose a stent having a drug where "the first or second end of the stent is **free from any drugs**." Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and teaches nothing regarding the amount of drug applied to different portions of the stent.

15. Claim 67

Fischell et al. does not disclose a stent having a drug where "**a concentration of a drug carried by the stent is greater at the middle segment of the stent as compared to the first or second end.**" Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and certainly does not teach that the concentration of the drug carried by the stent varies in different portions of the stent.

16. Claim 68

There is nothing in Fischell et al. to even suggest that the "anti-thrombogenic coating" would include a **polymer**.

17. Claim 69

Fischell et al. does not disclose a method of forming a coating on a stent that includes "applying a composition having a drug to a selected portion of the stent to form a coating, wherein **the concentration of the drug in the coating** is greater at the middle segment as compared to the first or second end." Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and certainly does not teach that the concentration of the drug in the coating varies in different portions of the stent.

18. Claim 70

Fischell et al. does not disclose a method of producing a medicated stent that includes, "depositing a drug along the middle segment of the stent, wherein at least one of the ends is **free from any drugs**." Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and certainly does not disclose that at least one the ends is free from drugs.

19. Claim 71

Fischell et al. does not disclose a method of producing a medicated stent that includes, "depositing a drug along the middle segment of the stent, wherein **at least one of the two ends has less drug than the middle segment**." Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and teaches nothing regarding the amount of drug applied to different portions of the stent.

20. Claim 83

Fischell et al. does not disclose a stent having a drug where "**a concentration of a drug carried by the stent is greater at the first or second end of the stent as compared to the middle segment**." Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and certainly does not teach that the concentration of the drug carried by the stent varies in different portions of the stent.

21. Claim 85

Fischell et al. does not disclose a method of forming a coating on a stent that includes "applying a composition having a drug to a selected portion of the stent to form a coating, wherein **the concentration of the drug in the coating is greater at the first or second end as compared to the middle segment.**" Fischell et al. merely discloses applying an anti-thrombogenic coating on the stent, and certainly does not teach that the concentration of the drug in the coating varies in different portions of the stent.

Claim Rejections – 35 U.S.C. § 103

A. Fischell et al.—Claim 30

The Examiner has rejected Claim 30 under 35 U.S.C. §103(a) as being unpatentable over Fischell et al. As noted above, Claim 21 is allowable over Fischell et al. Claim 30 depends directly from Claim 21, and is allowable for at least the same reason.

CONCLUSION

Claims 1, 3, 5-7, 10-32, 37-39, 41-44 and 46-50, 53-59, 61 and 63-85 are pending in this application. Examination and allowance of the claims are respectfully requested.

Also, as requested in the Response to Office Action filed on December 15, 2003, **Applicants respectfully request the Examiner to initial the Serruys reference ("I Like The Candy, I Hate The Wrapper" Circulation, (Jan. 2000)) that was cited in the Information Disclosure Statement filed on June 22, 2001**. According to the PTO-1449 form included with the Office Action mailed August 15, 2003, the other references for the IDS were considered on August 7, 2003; however, the Examiner's initials are not shown next to the Serruys reference.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

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